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ATTORNEYS FOR PLAINTIFF
MEDA PHARMACEUTICALS INC.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

MEDA PHARMACEUTICALS INC.,
Plaintiff,

vs.

ZYDUS PHARMACEUTICALS USA, INC.,
Defendant.

Civil Action No. _____

COMPLAINT

Plaintiff Meda Pharmaceuticals Inc. ("Meda"), for its Complaint against
Defendant Zydus Pharmaceuticals USA, Inc. ("Zydus"), hereby alleges as follows:

Parties

1. Plaintiff Meda is a Delaware corporation having a place of business at 265
Davidson Avenue, Somerset, New Jersey 08873.

2. Upon information and belief, Defendant Zydus is a New Jersey corporation having a place of business at 210 Carnegie Center, Suite 103, Princeton, New Jersey 08540.

Nature of the Action

3. This is a civil action for the infringement of United States Patent No. 5,164,194 ("the '194 Patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. §1 *et seq.*

Jurisdiction and Venue

4. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over Zydus by virtue of, *inter alia*, the fact that Zydus is a New Jersey corporation.

6. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

The Patent

7. On November 17, 1992, the '194 Patent, titled "Azelaastine Containing Medicaments," was duly and legally issued to Asta Pharma AG as assignee. Since August 16, 2002, Meda has been, and continues to be, the sole owner of the '194 Patent and the sole owner of the right to sue and to recover for any infringement of that patent. A copy of the '194 Patent is attached hereto as Exhibit A.

Acts Giving Rise to this Action

8. Upon information and belief, on or after November 14, 2005, Zydus submitted Abbreviated New Drug Application ("ANDA") 91-409 to the United States Food and Drug Administration ("FDA") under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)).

9. ANDA 91-409 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale, and sale of a generic azelastine hydrochloride nasal spray product, 0.125 mg (base)/spray, for use in treating, *inter alia*, seasonal allergic rhinitis ("the Generic Product"). ANDA 91-409 specifically seeks FDA approval to market the Generic Product prior to the expiration of the '194 Patent.

10. ANDA 91-409 alleges under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '194 Patent are invalid and/or not infringed by the manufacture, use, or sale of the Generic Product. Meda received written notification of ANDA 91-409 and its § 505(j)(2)(A)(vii)(IV) allegation on February 8, 2010.

11. Zydus's submission of ANDA 91-409 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '194 Patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Zydus commercially manufactures, uses, offers to sell, or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct during the term of the '194 Patent, it would further infringe the '194 Patent under 35 U.S.C. § 271(a), (b) and/or (c).

12. Zydus had actual and constructive notice of the '194 Patent prior to filing ANDA 91-409.

13. Meda will be irreparably harmed by Zydus's infringing activities unless those activities are enjoined by this Court. Meda does not have an adequate remedy at law. Both the balance of the hardships as between Meda and Zydus and the public interest further support this Court enjoining Zydus's infringing activities.

Prayer for Relief

WHEREFORE, Meda prays for judgment as follows:

- A. That Zydus has infringed the '194 Patent;
- B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA 91-409 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration date of the '194 Patent, including any extensions;
- C. That Zydus, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, or selling the Generic Product within the United States, or importing the Generic Product into the United States, prior to the expiration of the '194 Patent, including any extensions;
- D. That Meda be awarded monetary relief if Zydus commercially manufactures, uses, offers to sell, or sells the Generic Product within the United States, or imports the Generic Product into the United States, prior to the expiration of the '194 Patent, including any extensions, and that any such monetary relief be awarded to Meda with prejudgment interest;

E. That Meda be awarded the attorney fees, costs and expenses that it incurs prosecuting this action under 35 U.S.C. § 285; and

F. That Meda be awarded such other and further relief as this Court deems just and proper.

Dated: March 22, 2010

/s/ Thomas R. Curtin

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